K112141
Page 1 of 2

APR 13 2012

510(k) Summary

Castle Laser Systems Limited

Submitter's Contact Information

Name:	Raymond R. Blanche
Address	NST Consulting, LLC 641 Shunpike Road, Suite 311 Chatham, New Jersey, 07928
Telephone: Facsimile:	(973) 539-7444 (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name:	CLS001 Laser System
Sponsor Contact Information:	David Smith Castle Lasers Systems Limited 64 Dudley Street Bedford Bedfordshire, MK40 3TB United Kingdom
Common or Usual Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48

Predicate Devices:

Device Trade Name	**Manufacturer**
Smartepil	Cynosure, Inc.
Depilase Yag Lase Plus	Depilase Group Ltd

Date Prepared:	July 15, 2011 Updated April 12, 2012

Intended Use / Indications for Use

The CLS001 Laser System is indicated to effect stable, long-term or permanent hair reduction, in Fitzpatrick skin types I-VI, including sun tanned skin types. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing after a treatment regime The CLS001 Laser System is intended to effect coagulation and haemostatis of vascular lesions in Fitzpatrick skin types I-VI, including suntanned skin types.

Technological Characteristics

The CLS001 Laser System is an analog, pulsed Nd: YAG laser utilizing the Nd: YAG crystal as the lasing medium. It operates at the wavelength of 1064 nanometers. Laser activation is controlled by a footswitch mechanism. Physically, the system weighs 66 pounds, is 13.8 inches high, 23.6 inches wide and 17.3 inches deep. The electrical requirements are 220/240 VAC single phase, 50/60 Hz and 8 amps.

Performance Data:

Clinical Performance Data: none required

Non-clinical Performance Data: Manufactured according to cGMP per Guide to CGMP, WHO/VSQ/97.02

Substantial Equivalence

The CLS001 Laser System is as safe and effective as the other devices in its class, the Smartepil and the Depilase. The sponsor believes that with the exception of the configuration of the predicate devices, the devices are identical in the key areas that effect safety and efficacy. Both The sponsor believes that the difference in the physical appearance or in the method of delivering the radiant energy of the device systems is of no consequence and does not effect the therapeutic value or the safety profile. The sponsor believes that the difference between the devices is limited to the method of controls. The CLS001 is an analog system and the predicate devices are digital, microprocessor controlled systems. The CLS001 laser system is another safe and effective Nd:YAG laser intended to effect stable, long-term or permanent hair reduction, in Fitzpatrick skin types I-VI, including sun tanned skin types. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing after a treatment regime The CLS001 Laser System is intended to effect coagulation and haemostatis of vascular lesions in Fitzpatrick skin types I-VI, including suntanned skin types. Therefore, the CLS001 Laser System satisfies the FDA's substantial equivalence criteria and should be granted a 510(k) clearance for marketing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Castle Laser Systems, LTD
% NST Consulting, LLC
Mr. Raymond R. Blanche
Managing Member
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

APR 13 2012

Re: K112141
Trade/Device Name: Caste Laser Long Pulse Nd: YAG CLS001
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 28, 2012
Received: March 7, 2012

Dear Mr. Blanche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K 112141

Device Name: Castle Laser Long Pulse Nd:YAG Laser CLS001

Indications for Use:

The CLS001 Laser System is intended to effect stable, long-term or permanent hair reduction, in Fitzpatrick skin types I-VI, including sun tanned skin types. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing after a treatment regime

The CLS001 Laser System is intended to effect coagulation and haemostatis of vascular lesions in Fitzpatrick skin types I-VI, including suntanned skin types.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED)

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use X OR Over-the -Counter Use_____
(Part 21 CFR 801 Subpart D)

for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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